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1487 '00 JAN -3 AT1:42  
12/17/99

Dockets Management Branch HFA 305  
Food and Drug Administration  
5360 Fishers Lane Room 1061  
Rockville, MD 20852

RE: Docket #97N-484S  
Suitability Determination for Donors of Human and Cellular Tissue-Based Products

To Whom It May Concern:

On behalf of the patients in Indiana I wish to express my strong opposition to the proposed requirement that all donor egg/IVF cycles must undergo cryopreservation and quarantine for 6 months prior to embryo transfer. There is no scientific basis or medical evidence to support this requirement.


The current strategy to rescue "clean" and healthy offspring from infected animals is to perform embryo transfer. This approach has been used successfully in animal husbandry for years. There is no evidence that infectious organisms are transferred via the human oocyte. There have been no incidence of disease transmission using human oocytes as the vector.

This proposed rule adds significant medical expense, additional procedures and potential for reduced clinical outcomes. It delays a patients opportunity for pregnancy and adds to the emotional stress these patients experience, without any documented evidence of benefit.

We are all very concerned about ensuring the health of patients using donor services, as well as the health of any potential offspring. However, it seems that current screening practices are identifying healthy donors without adverse impact on patient care. The proposed rule is not warranted and adversely impacts patient care.

On behalf of our patients, I urge you to reconsider such a position and to work more closely with knowledgeable organizations such as ASRM and SART to ensure that donor IVF practices both ensure patient health and quality outcomes. As presented however, the current plan fails to meet this need.


Respectfully,



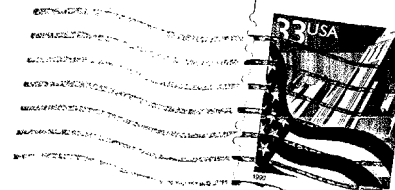
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97N 484S

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